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|---|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/771,853  | 02/04/2004  | Larry A. Sklar       | N12-035US           | 3509             |
| 7590  | 04/03/2006  | EXAMINER             |                     |                  |
| Henry D. Coleman<br>714 Colorado Avenue<br>Bridgeport, CT 06605 |             |                      | SHAFER, SHULAMITH H |                  |
|   |             | ART UNIT             | PAPER NUMBER        |                  |
|   |             | 1647                 |                     |                  |

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b>     | <b>Applicant(s)</b> |  |
|------------------------------|----------------------------|---------------------|--|
|                              | 10/771,853                 | SKLAR ET AL.        |  |
|                              | <b>Examiner</b>            | <b>Art Unit</b>     |  |
|                              | Shulamith H. Shafer, Ph.D. | 1647                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 04 February 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-55 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) \_\_\_\_\_ is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) 1-55 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

## DETAILED ACTION

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 1-26, drawn to an assay for binding of G-protein, GPCR and ligand, using G-protein beads classified in class 435, subclass 7.1.
- II. Claims 27-40, and 54, drawn to a method of evaluating a G protein-coupled receptor agonism or antagonism of a compound by a bead based flow cytometric process, classified in class 435, subclass 7.1.
- III. Claims 41 and 55 drawn to a method of evaluating a library of compounds, classified in class 435, subclass 7.1.
- IV. Claims 42-47, drawn to a method of evaluating a GPCR agonism, antagonism or inactivity in a single sample by flow cytometric process, classified in class 435, subclass 7.1.
- V. Claims 48-53, drawn to a method of identifying agents useful in treatment of a disease, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons:

Inventions I-V are drawn to five patentably distinct processes with different goals, different intermediate steps and utilize different products (MPEP § 806.04, MPEP § 808.01).

Invention I recites a binding assay utilizing G-protein beads and detecting the formation of a stable ligand-receptor-G protein complexes by flow cytometry. The methods of Invention I are distinct from those of Inventions II-V. These methods each require different equipment, reagents and protocols. The methods of Invention I are

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distinct from those of Inventions II and IV which recite evaluation of GPCR agonism or antagonism, a step not required by the methods of Invention I. Thus, the search of the methods of Invention I and those of Invention II and IV would not be co-extensive.

The methods of Invention I and those of Invention III are distinct. Invention III recites the use of a library of compounds, a method step not required by Invention I. The search of the methods of Invention I and those of Invention III would therefore not be co-extensive.

The methods of Invention I and those of Invention V are distinct. Invention V requires a search of the appropriate patient population, and would not be coextensive with the search for the methods of Invention I.

The methods of Inventions II, and IV both recite evaluation of GPCR agonists or antagonists. However, the methods of Invention II are distinct from those of Invention IV. Invention II is drawn to a method of evaluating a GPCR agonist or antagonist using high throughput systems whereas Invention IV recites a method of evaluating a GPCR agonist or antagonist in a single sample. The methods of Invention II requires different equipment and protocols and would thus require distinct searches of the art from those of Inventions IV.

The methods of Invention II and those of Invention III are distinct. Invention III recites the use of a library of compounds, a method step not required by Invention II. The search of the methods of Invention II and those of Invention III would not be co-extensive.

The methods of Invention II and those of Invention V are distinct. Invention V requires a search of the appropriate patient population, and would not be coextensive with the search for the methods of Invention VIII. Each method (II-V) would require a unique search for the art which would present an undue burden on the Examiner and the resources of the USPTO.

The methods of Invention III and those of Inventions IV and V are distinct. Invention III recites the use of a library of compounds, a method step not required by

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Inventions IV and V. The search of the methods of Invention III and those of Invention IV and V would not be co-extensive. Furthermore, the methods of Invention V requires a search of the appropriate patient population, and would not be coextensive with the search for the methods of Invention III. Each method (III-V) would require a unique search for the art which would present an undue burden on the Examiner and the resources of the USPTO.

The methods of Invention IV are distinct from those of Invention V. Invention V requires a search of the appropriate patient population, and would not be coextensive with the search for the methods of Invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer whose telephone number is 571-272-3332. The examiner can normally be reached on 8 AM to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHS



LORRAINE SPECTOR  
PRIMARY EXAMINER